IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION

IN RE: ETHICON, INC. PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION **THIS DOCUMENT RELATES TO:** **WAVE 4 CASES LISTED IN DEFENDANTS' EXHIBIT A**	**Master File No. 2:12-MD-02327** **MDL No. 2327** **JOSEPH R. GOODWIN** **U.S. DISTRICT JUDGE**

PLAINTIFFS' OPPOSITION TO DEFENDANTS' MOTION TO EXCLUDE THE OPINIONS AND TESTIMONY OF HOWARD JORDI, PH.D.

Dr. Howard Jordi's opinions in this matter mirror the opinions he has expressed in other cases. Other than excluding opinions derived exclusively from his testing of third party explants, this Court has approved Dr. Jordi's testimony *in toto* consistently. Despite this fact, defendants once again attack Dr. Jordi's opinions in a very limited manner. While defendants continue with their attempts to couch their arguments in phraseology somewhat differently from their prior briefs, their arguments are nevertheless those this Court has previously considered and rejected.

I. BACKGROUND

Dr. Jordi has an undergraduate degree and a PhD in biochemistry. (Exhibit 1 at 1)[1] He is the founder, president and CEO of Jordi Labs, which specializes in the analysis of polymers, including polypropylene. (*Id.*) Dr. Jordi has developed and employed hundreds of analytical methods for evaluating polymers, including polypropylene. (*Id.*) In fact, in addition to his 40 years studying polymers in general, he has devoted 25 years to studying polypropylene in

[1] For ease of reference, Dr. Jordi's expert report is attached as Exhibit 1. His deposition transcript from the *Bellew* case is Exhibit 2.

particular. (*Id.*) Dr. Jordi has explained in painstaking detail how the TVT degrades and cracks. (Exhibit 1 at 5-17)

II. ARGUMENT AND AUTHORITY

I. This Court has already ruled on the reliability of Dr. Jordi's degradation opinions and found them to be reliable.

Defendants claim that Dr. Jordi's opinions are unhelpful and speculative because there is no reliable evidence showing when the alleged degradation becomes clinically significant. However, defendants conveniently overlook that this Court has already heard and ruled on this issue. This Court addressed this very issue in its Memorandum Opinion and Order in the Bellew case:

> The defendants also appear to make a reliability argument regarding Dr. Jordi's degradation opinions. However, in his expert report, Dr. Jordi describes numerous tests he performed on Ms. Bellew's mesh explant, and subsequently concludes that based on his review of the scientific literature and his knowledge, training, and experience in polymer science, "This level of degradation will have a *strong impact* on fiber mechanical properties." (Jordi Report [Docket 135], at 22). Accordingly, I **FIND** Dr. Jordi's opinions regarding the mechanical effects of degradation sufficiently reliable under *Daubert*.

Memorandum Opinion and Order [ECF No. 265], *Bellew v. Ethicon Inc., et al.*, No. 2:13-cv-22473 (S.D. W. Va. Nov. 20, 2014), at 9-10.

Similarly, this Court also addressed the matter in Wave 1 which was later adopted in Wave 2:

> Basically, Ethicon argues that degradation is only relevant if the expert can link it to some type of complication. I reject this argument. A single expert need not provide all the pieces of the puzzle for their testimony to be useful to the jury in determining the ultimate issues in the case. *See, e.g., Huskey v. Ethicon, Inc.*, 29 F. Supp. 3d 691, 710 (S.D. W. Va. 2014) (rejecting a similar argument and stating "general causation opinions are helpful to the jury and fit the facts of the case regardless of whether the plaintiff may ultimately fail to carry their burden to show that [the plaintiff] was harmed"). Ethicon's Motion in this regard is DENIED.

Memorandum Opinion and Order [ECF No. 3278], Wave 1 (S.D. W. Va. Dec. 16, 2016, at 6.

Accordingly, the reliability of Dr. Jordi's degradation opinions has already been established by this Court and should not be addressed again.

A. Dr. Jordi Will Not Testify as to His Testing of Meshes Formerly Implanted in Third Parties.

The Court has spoken on this matter and neither plaintiffs nor Dr. Jordi will act inconsistently with that ruling.

B. Dr. Jordi's Opinions Regarding Prolene Sutures are Based on a Thorough Review of the Evidence and Defendants Are Not Entitled to Introduce FDA Actions into Evidence.

Defendants do not challenge Dr. Jordi's degradation opinions regarding mesh except to the extent that they apply to sutures. Dr. Jordi opines that polypropylene degrades. Granted, when it degrades as a single-filament suture, minimal damage may occur. When it degrades as a mesh composed of countless filaments, more damage may occur. The latter is for medical experts to opine. Dr. Jordi will testify only that polypropylene degrades generally and defendants' mesh degrades specifically.

Dr. Jordi's opinion about degradation is not somehow preempted. First of all, there is no such animal as opinion preemption. Only claims or causes of action can be preempted. Perhaps an opinion inconsistent with a federal agency ruling might be deemed irrelevant or otherwise inadmissible, but it is not "preempted." Further, the same reasoning does not lead to the conclusion that Dr. Jordi's testimony on the same would be inappropriate. Moreover, there is nothing inconsistent between Dr. Jordi's criticism of polypropylene as used in mesh and the

FDA's approval of a single polypropylene fiber in a suture. As this Court has repeated time and time again in its preemption orders:

> Although Ethicon represents that the products are primarily composed of the same material, it does not automatically follow that the material is safe in both devices. The Prolene suture is a nonabsorbable surgical suture; the [Prolift] is a form of transvaginal mesh. The consists of a single filament of polypropylene; the [Prolift] is a mesh woven from knitted Prolene filaments. The average Prolene suture is a few inches long; the [Prolift] contains many times the amount of polypropylene material. The Prolene suture is not intended to adhere to human tissue; the [Prolift] is designed to adhere to human tissue. The Prolene suture is designed to be easily pulled out of the body; the [Prolift] cannot be removed without invasive surgery....

Bellew v. Ethicon, Inc., Civ. Act. No.: 2:13-cv-22473, 2015 WL 6674424, at *3 (S.D.W. Va. Nov. 24, 2014) (*quoting Lewis v. Johnson & Johnson*, 991 F. Supp. 2d 748, 757-58 (S.D.W. Va. 2014); *Huskey v. Ethicon, Inc.*, 29 F. Supp. 3d 736, 747 (S.D.W. Va. 2014)).

In other words, the fact that the complications of a single filament, standing alone as a suture, do not create dire consequences does not mean that a mass of such filaments suffering from the same consequences would not. The FDA never considered the safety of polypropylene as a mesh and thus its approval of sutures does not warrant restricting Dr. Jordi's testimony, any more than it warrants a finding of preemption.

> In another attempt to secure preemption, Ethicon next contends that because a component of the Prolift has surpassed the FDA's vigorous premarket approval process, the plaintiff's design defect claims tied to that component are preempted, even though the device as a whole has not received FDA approval. In *Lewis*, I rejected this argument on the basis that "[p]ersuasive authority from other district courts ... indicates that the preemption analysis is not applied differently to the component parts of a medical device and the medical device itself." *Lewis*, 991 F.Supp.2d at 759 (quoting *Gavin v. Medtronic, Inc.*, CIV.A. 12–0851, 2013 WL 3971612, at *11 (E.D.La. July 19, 2013)). Put simply,
>
> > [t]o require that a distinction be drawn between the approval process of the individual components of a system and the system itself, would, it seems, add a level of complication to the medical device approval process not anticipated by Congress, the FDA, or

> medical device manufacturers. [Quotation marks and citation omitted]. "It makes no sense—indeed, it would probably be impossible—to pick apart the components of a medical device and apply different preemption analyses to different components." *Riley*, 625 F.Supp.2d at 780. Determining preemption based upon the component parts of a device, rather than the device as a whole, would create a legal quagmire whereby tort claims against one part of a device are preempted while tort claims against another part of a device are not.

Lewis, 991 F.Supp.2d at 760; *Huskey*, 2014 WL 3362287, at *10 (quoting Lewis). Considering FDCA preemption separately as to each component of a medical device "would create a doctrine that forces courts to dissect every medical device." *Lewis*, 991 F.Supp.2d at 760. Such an approach "would only serve to create chaos in a field that is already difficult to navigate." *Id.* As I explained previously,

> bright line rules are important to create clarity for all parties involved.... Each involved party should be able to determine whether tort claims regarding a medical device are preempted based upon the review process the device actually went through. If the [Prolift] had gone through the premarket approval process while the polypropylene filament had gone through the 510(k) process, I cannot imagine that Ethicon would think the component parts of a device should be analyzed separately from the device itself.... Just as "a device receiving premarket approval cannot be separated into its component parts to avoid application of express preemption," *Gross*, 858 F.Supp.2d at 487, a device receiving 510(k) approval cannot be separated into its component parts to create express preemption.

Id. at 760; *Huskey*, 2014 WL 3362287, at *10 (quoting *Lewis*). This piecemeal application of federal preemption doctrine is exactly what Ethicon asks the court to declare, (*see* Mem. in Supp. [Docket 125], at 17 (explaining that its "preemption motion is expressly limited to claims stemming from the use of Prolene polypropylene material in the body ... *not* to other properties of the device or the device as a whole")), and for the above reasons, I refuse to employ FDCA preemption in this manner.

Bellew, 2014 WL 6674424, at *4 (S.D.W. Va. Nov. 24, 2014).[2]

[2] *See also*, Memorandum Opinion and Order [ECF No. 3278], Wave 1 (S.D. W. Va. Dec. 16, 2016, at 6-7.

B. Dr. Jordi's Opinions on Brittleness, Environmental Stress Cracking and other Mechanical Properties Are Reliable.

Defendants have previously challenged Dr. Jordi's opinion on the brittleness of their mesh, and this Court has rejected those challenges. *See, e.g.*, Memorandum Opinion and Order (*Daubert* Motions), *Bellew v. Ethicon, Inc.*, Civ. Act. No. 2:13-cv-22473, Document No. 265 (Nov. 20, 2014) at 8, 15), *see also* Memorandum Opinion and Order [ECF No. 3278], Wave 1 (S.D. W. Va. Dec. 16, 2016, at 7. The Court has also rejected the principal basis of defendants' criticism which is that Dr. Jordi has found degradation only on the surface of mesh. As the Court held in *Bellew*, if defendants contend that is an issue, they can certainly note the limitations of Dr. Jordi's analysis at trial. *Id.* at 10. The Court has also rejected challenges to Dr. Jordi's opinion that mesh degrades. *Id.* at 8.

Dr. Jordi's opinion on brittleness is amply supported by the evidence of mesh cracking. Such cracking causes brittleness by degrading the mesh, as Dr. Jordi explains. (X1 at 23) Oxidation makes the mesh brittle. (Exhibit 2 at 90:3-7; 92:1-93:7) Dr. Jordi's opinion is based on the medical literature which clearly establishes embrittlement. (Exhibit 2 at 93:14-20)

This Court rejected defendants' challenge on environmental stress cracking in the *Bellew* case. (*Bellew* Order, *supra*, at 10-11) Dr. Jordi's expert report in the *Bellew* case explains that environmental stress cracking (or ESC) "is cracking of a polymer due to the combined action of a stress and a fluid." (Exhibit 3 at 5) When biological fluids, such as fatty acids and cholesterol esters, are absorbed into the mesh fiber, they can cause amorphous (susceptible – either through oxidative microcracks or a decrease in crystallinity) regions of the fiber to crack from the strain in the compromised areas of the fiber. Dr. Jordi also relies on peer-reviewed publications. (Exhibit 4--Clave, H., et al., *Polypropylene as a reinforcement in pelvic surgery is not inert: comparative analysis of 100 explants*. Int. Urogynecol. J., Vol. 21(3), 261-70 (2010)) He cites

similar data in his report in this case. (X1 at 5-6) Dr. Jordi explains in detail how his own work has revealed that fatty acids and cholesterol esters result in environmental stress cracking. (Exhibit 2 at 85:2-21; 92:4-93:7))

Moreover, defendants do not deny environmental cracking; rather, they merely argue Dr. Jordi does not adequately defend the mechanism by which environmental stress cracking occurs. Though erroneous in light of Dr. Jordi's report, it is difficult to see the relevance of this argument since the problem constitutes a defect with defendants' product regardless of the mechanism by which it occurs.

III. CONCLUSION

Defendants pose no arguments against Dr. Jordi's testimony that this Court has not already rejected. Dr. Jordi's opinions regarding the defects in defendants' polypropylene mesh have not changed since his court-approved testimony in previous cases. His testimony is well-grounded in medical literature and his own research independent of his analysis of third party explants. Defendants' motion should thus be denied in its entirety.

Dated: April 27, 2017.

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on April 27, 2017, I electronically filed the foregoing document with the Clerk of the court using CM/ECF system which will send notification of such filing to the CM/ECF participants registered to receive service in this MDL.

Respectfully submitted,

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